

January 29, 2009

The Honorable Ron Stoker
Chairman,
Judiciary Committee
Capitol Station
Helena, Montana 59620

RE: Opposition to House Bill 288 - An Act Banning Human Cloning

Dear Mr. Chairman:

On behalf of the Biotechnology Industry Organization (BIO), I would like to express concern with House Bill 288, an act to ban human cloning in Montana. BIO fully supports a prohibition on human reproductive cloning. At this time we see no ethical or medical justification for the replication of an existing or previously existing human being. However, House Bill 288 goes beyond preventing human reproductive cloning. This legislation will prohibit a very promising area of research that could lead to treatments and possibly cures for diseases afflicting millions of people worldwide.

Medical research has taken quantum leaps in the past decade. Scientists are identifying and developing treatments, and potentially cures, for deadly and seriously debilitating diseases. Cloning techniques have been invaluable in research leading to the production of breakthrough medicines, diagnostics and vaccines to treat heart attacks, various cancers, kidney disease, diabetes, hepatitis, multiple sclerosis, cystic fibrosis, and other diseases. The cloning of genes already has contributed to the development of important medicines, such as tissue plasminogen activator (tPA) to dissolve clots after a heart attack and erythropoietin (EPO) for anemia associated with dialysis for kidney disease.

While we categorically oppose human reproductive cloning, we are working closely with researchers and patient communities to promote the very promising field of stem cell research. Human stem cells, both adult and embryonic, hold significant potential to help scientists develop treatments and regenerate damaged or diseased cells.

Stem cells can be derived from multiple sources. Adult stem cells can be isolated from several sources within the human body. Recent advances in stem cell research have yielded a very promising development called induced pluripotent stem (iPS) cells. Scientists have been able to reprogram adult cells to exhibit embryonic stem cell characteristics. This advancement would not have been possible without the vast body of scientific knowledge scientists have been able to generate from the various fields of stem cell research.

The process of somatic cell nuclear transfer (SCNT) is one method researchers are using to develop embryonic stem cells. SCNT allows researchers to remove the nucleus from a donor egg cell and replace it with the nucleus from the cell of a potential patient. The cell is then stimulated to begin the cell division process that will create human stem cells that are genetically identical to the individual seeking treatment. This can be instrumental in improving the effectiveness of the treatment as a patient is technically being treated with his or her own cells. Immune system rejection of foreign cells is one of the major challenges confronting the potential effectiveness of stem cell treatments. Stem cells generated through SCNT could potentially address that problem.

There is no denying that this is a complex ethical issue which has become politically divisive. Our industry feels that the potential benefit of the research is compelling. We urge the Montana Legislature to enact legislation that bans human reproductive cloning -- cloning to create a child -- but allow SCNT for therapeutic purposes. One of the most thoughtful approaches to addressing this complicated issue comes from Senator Orrin Hatch of Utah - and ardent Pro-life member of the US Senate:

“At the core of my support for regenerative medicine research is my belief that human life requires and begins in a mother’s nurturing womb.

“As I considered the ethical appropriateness of nuclear transplantation in regenerative medicine research, two facts stood out:

- * The egg, with its nucleus removed, is never fertilized with sperm;
- * The resulting unfertilized, electrically activated embryo will not be implanted into a woman’s womb so there is no chance of a birth. I should add that our bill would prevent implantation into any type of artificial womb that may one day be developed.

“The absence of a fertilized egg coupled with a legal prohibition against implantation leads me to conclude that this research can be conducted, with appropriate safeguards, in an ethically proper fashion.

“Should we continue other forms of stem cell research, such as adult stem cell research? Absolutely. I hope that adult stem cell research lives up to its promise. But should we cut off the promising avenue that embryonic stem cell research holds out? The answer to me is clear: no.”

Senator Hatch joins numerous scientific organizations as well as 40 Nobel prize winners in support of stem cell research and SCNT. The National Academy of Sciences (NAS) has concluded:

“The scientific and medical considerations that justify a ban on human reproductive cloning at this time are not applicable to nuclear transplantation to produce stem cells. Because of the considerable potential for developing new medical therapies to treat life-threatening diseases and advancing biomedical knowledge, the panel supported the conclusion of a previous National Academies’ report—*Stem Cells and the Future of Regenerative Medicine*—that recommends that biomedical research using nuclear transplantation to produce stem cells be permitted.”

If the intent of the Montana Legislature is to prohibit human reproductive cloning, but continue to allow for advances in all areas of stem cell research, we suggest that the following changes be made to House Bill 288:

1 Amend the definition of Human Cloning in Section 1(4) to read:

(4) "Human cloning" means human asexual reproduction, accomplished by introducing the genetic material from one or more human somatic cells into a fertilized or unfertilized oocyte from which nuclear material has been removed or inactivated ~~to produce a living organism, at any stage of development, that is genetically virtually identical to an existing or previously existing human organism.~~ FOR THE PURPOSE OF IMPLANTING THE RESULTING PRODUCT TO INITIATE OR ATTEMPT TO INITIATE A PREGNANCY THAT COULD RESULT IN THE BIRTH OF A HUMAN BEING.

2 In Section 3(1) DELETE "other than human embryos" to read:

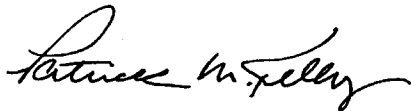
Section 3. Scientific research -- exception. (1) [Sections 1 and 2] do not restrict areas of scientific research not specifically prohibited by [sections 1 and 2], including research into the use of nuclear transfer or other cloning techniques to produce molecules, deoxyribonucleic acid, tissues, organs, plants, cells ~~other than human embryos~~, or animals other than humans.

The bioscience industry is working diligently to improve healthcare by developing treatments and hopefully soon cures for numerous diseases. Major advances in new and innovative treatments are occurring every day, particularly in the area of stem cell research. The industry needs to continue to employ all tools necessary to expand our knowledge of medicine and healthcare. In the words of a preeminent researcher in the field of stem cells:

"It's not our job to guess right now what we will need in the future. This is a war against disease and it needs to be fought with all weapons."

Sean Morrison, Professor of Cell and Developmental Biology, University of Michigan

Again, thank you for the opportunity to provide comments on House Bill 288. The changes we have recommended would prohibit reproductive cloning while preserving a very promising area of research that could one day lead to treatments and cures for a variety of diseases. I would be happy to answer any questions or provide additional information to you or the committee.



Respectfully,
Patrick M. Kelly
Vice President, State Government Relations
Biotechnology Industry Organization

BIO is the national trade organization representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products. In Montana, we work closely with the Montana BioScience Alliance to represent the state's emerging life science companies.